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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,077	04/16/2001	Bernhard Fleckenstein	514429-3647.1	6707
20999	7590	03/03/2004	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,077

Applicant(s)

FLECKENSTEIN ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-32 is/are pending in the application.
- 4a) Of the above claim(s) 5-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3 and 30-32 is/are rejected.
- 7) ☐ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

1. Amendment filed 11/18/2003 is acknowledged. Claim 4 is canceled. Claims 30-32 are added. Claims 1-3,5-32 are pending. Claims 5-29 remain withdrawn from further consideration

Claims 1-3, 30-32 are under consideration.

2. Applicants arguments with respect to rejection made under 35 U.S.C. 112-1 have been considered but are deemed moot in view of the new grounds of rejection. Rejections under 35 U.S.C. 102 are withdrawn in view of amendment to the claims. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 31,32 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly define the metes and bounds of the subject

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matter that will be protected by the patent grant . Claims 31,32: It is not clear from the claims what structure and location in the protein sequence is encompassed by the terms "immunoglobulin domain" and "transmembrane domain". Do these domains include the domain "having >40% similarity to Sema domain", or they are adjacent (on each side?). The specification, although providing particular examples, does not provide a standard for ascertaining the requisite composition, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1,3,30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims as amended are drawn to proteins that, as a core structure, have a sequence having 40-50% similarity to residues 45-545 of SEQ ID No. 3. As such, the

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claims encompass sequences from other species, mutated sequences, allelic variants, splice variants, etc. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support genus encompassed by the claims.

The only products disclosed in the specification is the protein SEQ ID No. 3 itself. No representative species of any other homologs are present. There is no guidance on what, if any, structure of homologs of SEQ ID No. 3 will satisfy the functional limitation of being "a semaphorin protein". This functional limitation "a semaphorin protein" is not informative in itself because specification does not clearly describe functional characteristics of a product that would clearly assign it as a member of semaphorin. For example, a feature of immunomodulating, referred to in specification as biological activity of semaphorins, is, to certain extent, a feature typical of any protein. Thus, in the absence of adequately described functional characteristics a fusion protein of factor X and albumin (referred to in the previous Office action and described in WO 01/77137) which is completely unrelated to semaphorins but can be an immunomodulator would satisfy the functional "limitation" of the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date

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sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Applicant is advised that absent factual evidence, a percentage sequence similarity of less than 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The specification does not disclose a representative number of species sufficient to demonstrate that applicant was in possession of the claimed invention at the time of filing.

5. Claims 1,3, 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising SEQ ID No. 3, does not reasonably provide enablement for polypeptides comprising domain having 40-50% similarity to residues 45-545 of SEQ ID No. 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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There is no guidance on what, if any, structure of homologs of SEQ ID No. 3 will satisfy the functional limitation of being "a semaphorin protein". The functional limitation "a semaphorin protein" is not informative in itself because specification does not clearly describe functional characteristics of a product that would clearly assign it as a member of semaphorin. For example, a feature of immunomodulating, referred to in specification as biological activity of semaphorins, is, to certain extent, a feature typical of any protein.

Therefore, in the absence of sufficient working examples, and in the absence of guidance in the specification, an artisan would not be able to make the product as claimed without undue experimentation.

6. Further, identifying a polypeptide as having a limited homology to the claimed polypeptides does not indicate what function it might have. Assignment to a prior art family of polypeptides is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific utility to the new member of the polypeptide family. Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) disclose that the skilled artisan is well aware that assigning functional activities for any particular polypeptide or polypeptide family based upon sequence homology is inaccurate, in part because of the multifunctional nature of polypeptides (see, e.g.,

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"Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two polypeptides, only experimental research can confirm the artisan's best guess as to the function of the structurally related polypeptide (see in particular "Abstract" and Box 2). Therefore, in the absence of sufficient working examples, and in the absence of guidance in the specification, an artisan would not be able to use the product as claimed without undue experimentation.

Conclusion.

7. No claims are allowed

Claim 2 is novel and unobvious over the prior art of record or any combination thereof. The prior art of record does not teach or suggest a polypeptide comprising SEQ ID No. 3.

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-

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0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

February 25, 2004

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.